

Announcement Number: CDRH-OSEL-DBCMS-168

Position Title: Materials Engineer, Chemical Engineer, Biomedical Engineer

Salary Range: \$77,490 to \$119,794 (depending upon education and experience)

Open Period: May 23, 2016 to June 17, 2016

Position Information: Full Time

Duty Location: Silver Spring, MD

Who may be considered: US Citizens and Permanent Residents

Job Summary:

The Office of Science and Engineering Laboratories (OSEL), the laboratory of the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA), is seeking a Materials Engineer, Chemical Engineer, or Biomedical Engineer in the Division of Biology, Chemistry and Materials Science (DBCMS). DBCMS is responsible for conducting research to support the Center's mission to assure the safety and effectiveness, and promote the improvement of medical devices in the areas of materials performance, microbiology and infection control, and toxicology and biocompatibility.

For additional information about CDRH regulatory science research:

<http://www.fda.gov/MedicalDevices/ScienceandResearch/default.htm>

Major duties and responsibilities:

1. Plan and conduct state-of-the-art materials research, develop innovative approaches to assess the safety, efficacy, and performance of medical device materials, and make recommendations to management and regulatory review staff pertaining to findings. The scope of the research encompasses computational materials modeling and laboratory validation studies.
2. Assess the performance of medical device materials in support of FDA regulatory programs through review of scientific data submitted by product sponsors. Serve as a technical expert and authority to the Center, Agency, and industry scientists related to the modeling and performance of medical device materials.
3. Develop and evaluate Agency-wide guidelines and guidance documents concerning the data required in submissions to the Center and Agency for clearance/approval. Consult with intra-Agency standards committees and standards-setting organizations to develop and review international consensus standards for the evaluation of medical devices.

4. Produce written products of high quality including professional papers that receive wide distribution within the scientific or professional community. Effectively communicate technical information regarding medical device materials performance issues through presentations to the medical and scientific experts in the Center and Agency.
5. Serve on FDA taskforces and/or work groups, as needed to address issues pertaining to assessing the safety and performance of medical device materials.

Educational Requirements:

Applicants should possess a Ph.D., or equivalent science degree in Materials Science and Engineering, Chemical Engineering, Biomedical Engineering, or related field. The applicant must also be able to demonstrate mastery of principles, practices, and theories in the field of Materials Science and Engineering, Chemical Engineering, and/or Biomedical Engineering that enables the incumbent to serve as a technical authority in the scientific analysis on the safety and effectiveness of medical devices and radiological products; provide an authoritative analysis of scientific data submitted to the Agency; and to develop new and innovative approaches to assess materials performance required for medical device reviews by FDA.

Applicants who have completed part or all of their education outside of the U.S. must have their foreign education evaluated by an accredited organization to ensure that the foreign education is comparable to education received in accredited educational institutions in the U.S. This evaluation must also be provided by midnight Eastern Time on the closing date of this vacancy announcement. For more information on Foreign Education verification, visit the [US Department of Education](#). Another listing of services that can perform this evaluation is available at the [National Association of Credential Evaluation Services \(NACES\)](#) website.

Qualifications: Please document knowledge, skills, and abilities relevant to each area described below:

1. Minimum two to five years of experience planning and conducting state-of-the-art theoretical and computational materials research. Preference will be given to applicants with experience conducting large-scale, multi-physics modeling studies that include in-vitro or in-vivo validation components.
2. Experience reviewing, analyzing, and using scientific data or other information to advance and convey understanding needed to assess the safety and performance of medical device materials.
3. Knowledge of the scientific principles, theories and practices associated with biomedical engineering, chemical engineering, and/or materials science for application to the safety and performance evaluation of medical device materials.
4. Ability to participate in and contribute to multi-disciplinary teams and work groups to resolve difficult or controversial research and regulatory questions/problems.

5. Excellent skills in written and oral communication.

HOW YOU WILL BE EVALUATED: This application will be evaluated by a Search Committee and will be prioritized according to how your education and experience compares to the needs of the position. Those determined to be "best qualified" will be referred to the selecting official for further consideration.

How to Apply:

To apply for this announcement, applicants must provide a complete application package which includes: (a) a cover letter with compensation requirements, (b) curriculum vitae, (c) responses that document knowledge, experience and skills in the five areas from the Qualifications section, and (d) the names and contact information of three references.

Note: All supporting documents should include the announcement number.

Applications should be sent via email to oselrecruitment@fda.hhs.gov or mailed to the attention of Gwen Gibbins, FDA/CDRH/OSEL, 10903 New Hampshire Avenue, Building 62, Room 4214, Silver Spring, MD 20993-0002. Applications must be received by closing date in order to be considered. Electronic submission of application materials is encouraged. Applications sent via e-mail must be submitted as MS Word, or Adobe pdf.

Contact Information for questions to Ms. Chirelle Taylor at Chirelle.Taylor@fda.hhs.gov

Additional Announcement Information

- 1. Security and Background Requirements:** If not previously completed, a background security investigation will be required for all appointees. Appointment will be subject to the applicant's successful completion of a background security investigation and favorable adjudication. Failure to successfully meet these requirements may be grounds for appropriate personnel action. In addition, if hired, a background security reinvestigation or supplemental investigation may be required at a later time. Applicants are also advised that all information concerning qualifications is subject to investigation. False representation may be grounds for non-consideration, non-selection and/or appropriate disciplinary action.
- 2. E-Verify:** If you are selected for this position, the documentation that you present for purposes of completing the Department of Homeland Security (DHS) Form I-9 will be verified through the DHS "E-Verify" System. Federal Law requires DHS to use the E-Verify System to verify employment eligibility of all new hires, and as a condition of continued employment, obligates the new hire to take affirmative steps to resolve any discrepancies identified by the system. The U.S. Department of Health and Human Services is an E-Verify participant.
- 3. Direct Deposit:** All Federal employees are required to have Federal salary payments made by direct deposit to a financial institution of their choosing.

4. **Benefits:** The Federal Government offers a comprehensive benefits package. Explore the major benefits offered to most Federal employees at <http://www.usajobs.gov/ei/benefits.asp#icc>
5. All qualification requirements must be met by the closing of the announcement.
6. Financial disclosure statement may be required.
7. One-year probationary period may be required.
8. Travel, transportation, and relocation expenses **will not** be paid.
9. Bargaining Unit Position: **Yes**
10. Drug Screening Required: **No**
11. Recruitment Incentive may be authorized: **No**